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| APPLICATION NO.         | FI                    | LING DATE       | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |  |
|-------------------------|-----------------------|-----------------|----------------------|---------------------|------------------|--|
| 09/683,405              | 09/683,405 12/21/2001 |                 | Carsten Rosenow      | 3447                | 2969             |  |
| 22886                   | 7590                  | 02/25/2004      |                      | EXAM                | EXAMINER         |  |
| AFFYMET                 | TRIX, INC             |                 | SIEW, J              | SIEW, JEFFREY       |                  |  |
|                         |                       | JNSEL, LEGAL DE | EPT.                 | . 25.12.15          | B. Bon M. Corn   |  |
| 3380 CENTRAL EXPRESSWAY |                       |                 |                      | ART UNIT            | PAPER NUMBER     |  |
| SANTA CLARA, CA 95051   |                       |                 |                      | 1637                | - Casalor C      |  |

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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|  | Application No.   | Applicant(s)   |  |  |  |  |  |
|--|---|--|--|--|--|--|--|
|  | 09/683,405  | ROSENOW ET AL.   |  |  |  |  |  |
| Office Action Summary  | Examiner  | Art Unit   |  |  |  |  |  |
|  | Jeffrey Siew  | 1637   |  |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |   |  |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPL' THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period of Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, however, may a reply be tin<br>y within the statutory minimum of thirty (30) day<br>will apply and will expire SIX (6) MONTHS from<br>, cause the application to become ABANDONE      | nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |  |  |
| Status   |   |  |  |  |  |  |  |
| 1) Responsive to communication(s) filed on 21 N  | <u>ovember 2003</u> .   | •  |  |  |  |  |  |
| <i>;</i> —   | <i>,</i> —  |  |  |  |  |  |  |
| , —  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. |  |  |  |  |  |  |
| closed in accordance with the practice under E   | Ex parte Quayle, 1935 C.D. 11, 4:   | 03 O.G. 213.   |  |  |  |  |  |
| Disposition of Claims  |   |  |  |  |  |  |  |
| <ul> <li>4)  Claim(s) 12-17,31 and 35-40 is/are pending in 4a) Of the above claim(s) is/are withdraw</li> <li>5)  Claim(s) 12-17 is/are allowed.</li> <li>6)  Claim(s) 31 is/are rejected.</li> <li>7)  Claim(s) 35-40 is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/o</li> </ul>   | wn from consideration.  |  |  |  |  |  |  |
| Application Papers   |   |  |  |  |  |  |  |
| 9) ☐ The specification is objected to by the Examine 10) ☑ The drawing(s) filed on 21 December 2001 is/a Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) ☐ The oath or declaration is objected to by the Example 11.  | re: a)⊠ accepted or b)⊡ object<br>drawing(s) be held in abeyance. See<br>ion is required if the drawing(s) is ob  | e 37 CFR 1.85(a).<br>lected to. See 37 CFR 1.121(d).   |  |  |  |  |  |
| Priority under 35 U.S.C. § 119   |   |  |  |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign  a) All b) Some * c) None of:  1. Certified copies of the priority documents  2. Certified copies of the priority documents  3. Copies of the certified copies of the priority documents  application from the International Bureau  * See the attached detailed Office action for a list  | s have been received.<br>s have been received in Applicati<br>rity documents have been receive<br>u (PCT Rule 17.2(a)).   | on No ed in this National Stage  |  |  |  |  |  |
| Attachment(s)  |   |  |  |  |  |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date   | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:  |  |  |  |  |  |  |

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## **DETAILED ACTION**

## Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kacian (US5,364,763 Nov. 15, 1994) in view of Lockhart et al (US6,040,138 march 21, 2000).

Kacian et al teach a method of sample preparation comprising obtaining a sample comprising a first type of cells and second type of cell wherein the first type is at least 10 times more suspeptible to lysis agent than second type (see whole doc. esp. col. 7 lines 45-50 where sodium deoxycholate is capable lysing white blood cells associated with mycorbacteriu leaving

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the mycobacteria cellularly intact). After lysis, he separates <u>all of the white blood cells</u> from mycobacteria (see col. 11 line s 56-60).

Kacian et al do not teach hybridizing to a plurality of different probes.

Lockhart et al teach performing hybridization assays using arrays with a mutlitude of different probes (see whole doc. esp. abstract). They teach concentrations of 5000 probes (see col. 3 line16). They teach beads (see col. 13 line 64).

One of ordinary skill in the art would have been motivated to apply Kacian isolated DNA from mycobacterium to Lockhart et al's array in order to monitor the expression of genes. As Kacian state that their method was designed for preparation of DNA for hybridization assays, it would have been <u>prima facie</u> obvious to apply Lockhart et al's hybridization arrays to the DNA isolated from Kacian in order to monitor the many different gene expressions.

### **SUMMARY**

2. Concerning claims 12-17 there is no prior art that teach the claimed method in which the first type of cell is animal and second type are plants cells or first type of cell is animal and second type are fungi or first type of cell is gram negative and second type are gram positive bacteria or first type of cell is yeast and second type are plant cells or bacterial cells. Concerning claims 35-40 are objected to for depending on rejected claim. If claim 31 were to be amended to recite the limitation of at least 5000 probes as discussed in the office action filed 5/21/03, the prior art rejection would be overcome.

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#### Conclusion

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number before January 22, 2003 is (703) 305-3886 and thereafter can be reached at 571-272-0787. The e-mail address is Jeffrey Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

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Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the <u>Tracey Johnson</u> for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and FAX (703)-308-4242.

JEPFREY SIEW PRIMARY EXAMINER

February 22, 2004